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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/508,045 03/03/00 MULLER

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QM12/1011

EXAMINER

JOHNSON, I

ART UNIT

PAPER NUMBER

3739

DATE MAILED:

10/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/508,045

Applicant(s)

MULLER ET AL.

Examiner

Hank Johnson

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 14-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 & 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION***Drawings***

The drawings are objected to under 37 CFR 1.83(a) because they fail to show the current density lines f and g in figure 1 as described in the specification (Page 9, line 5). Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Correction is required.

Figure 4 is objected to for not having the axis for the graphs labeled. On page 11, line 8 the disclosure refers to T(r) which is not shown in the figure.

Figures 5 and 6 are objected to because the graph lines are not labeled to clearly show which is power and which is impedance.

Figure 8 is objected to because the labels R, U and I in the figure are not defined.

Figure 9 includes the term FDM which is not described in the specification. Also the term "adaptation of electrical and thermal parameters" in the lower right box is not clearly defined.

Figure 11 has a label 87.7 that is not described in the specification. Label 87.6 is described as both the display unit (page 15, line 13) and a control procedure store (page 15, line 14 and Page 16, line 2).

Also in figure 11, a dotted control line is shown "to 83", the Fluid Container. Figure 8 shows no control or sensing to this component. Further, the lines to 85 (heater) and 84 (pump) are shown as inputs while in figure 8 these are dotted control (output) lines. Label 87.5 is described (page 15, line 12) as an input unit, yet Figure 11 shows no inputs. If this is intended to be a keyboard, it should be so labeled.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The

Art Unit: 3739

abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and **should not repeat information given in the title**. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it contains legal phraseology; specifically "said". Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: Numerous issues with wording used, examples include; Page 9, line 9 the word "spacing", suggest the word distance; Page 9, lines 20 – 22, the words "let" and "in dependence" are improper grammar.

The disclosure uses the terms ac, alternating current and HF source (power /generator) interchangeably. It is suggested a common terminology be used throughout the disclosure.

On page 14, line 5 the HF-generator is referred to as label 80 and the temperature sensor is referred to as label 81. Neither of these match those of Figure 8.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15, 17 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 15, the temperature is stated without a scale (centigrade).

In claim 17, the temperature control device is not clearly defined and conflicts with the drawings that clearly show other devices in the fluid source path to the electrode. It is not clear whether any control is accomplished in the fluid source (83).

In claim 23, the specification shows two calculation units (87.2 and 87.3) so it is not clear which unit is involved.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 14-26 rejected under 35 U.S.C. 102(a) as being anticipated by WO 96/34571 to Cosman et al.

Regarding claims 14 – 16; Cosman et al discloses an electrosurgical device for the electrothermal treatment of the human body with an electrode support, at least one electrode on the electrode support, an alternating current connected to the electrode with a controlled coolant source for the electrode and electrode support, the distal end of the electrode support being pointed, and a means for heating or cooling the electrode and electrode support independent of the alternating current source. The means for controlling the temperature of the thermal medium has the means to provide a wide range of temperatures such that heating and/or cooling could be achieved in the electrode and electrode support including specifically 30° and 37° centigrade.

Regarding claim 17; Cosman et al teaches an electrode and electrode support with a hollow cavity (Fig 2) and a fluid source in communication with the electrode and electrode support via a quantitative flow control device (pages 10 and 11).

Regarding claim 18; Cosman et al discloses embodiments using thermoelectric devices in the electrode tip (page 29, lines 16-21).

Regarding claims 19 - 24; Cosman et al teaches the use of computer assisted control using predetermined treatment plans (page 35, line 5), measured treatment parameters (Figure 8) and control of treatment parameters (page 35, line 4). The flexibility of the computer is further taught using table look-up of data (page 35, line 25), empirical data or calculated data (page 36, lines 10 and 11) to achieve desired results. The measured data includes a sensor in the tip for temperature input to the control system. The control process flow chart shown in figure 9 shows the control and verification algorithms.

Art Unit: 3739

Regarding claim 25; Cosman et al discloses a tubular electrode support of insulated structure (page 18, line 13 and Fig. 2A) and temperature sensor (Fig 2, # 23).

Regarding claim 26; Cosman et al teaches a two electrode embodiment (page 45, line 28).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 5,697,927 to Imran et al teaches an RF ablation electrode with controlled cooling and controlled RF application. U.S. Patent 5,906,613 to Mulier et al discloses an RF ablation electrode with delivery of a liquid to the electrode for either heating or cooling. U.S. Patent 5,735,846 to Panescu et al discloses an RF ablation treatment system with a temperature sensor in the probe, liquid cooling and a closed loop computer control of the process based on measured and stored parameters. U.S. Patent 5,643,197 to Brucker et al teaches an ablation catheter with a cooling fluid and U.S. Patent 5,620,479 to Diederich teaches an apparatus for thermal therapy using a probe with a point on its distal end, temperature sensor in the probe and computer control of the process using stored and measured parameters.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hank Johnson whose telephone number is (703) 305-0910. The examiner can normally be reached on Monday through Friday from 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Application/Control Number: 09/508,045

Page 6

Art Unit: 3739

Hmj
October 2, 2001



Lee Cohen
Primary Examiner

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a)

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.